UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

MARBETH WILDER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 2:20-CV-141-KAC-HBG
	)	
ETHICON, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This case is before the undersigned pursuant to 28 U.S.C. § 636, the Rules of this Court, and Standing Order 13-02.

Now before the Court is Defendants' Motion to Limit the Case-Specific Testimony of Bruce Rosenzweig, M.D. ("Motion to Limit") [Doc. 90] and Plaintiff's Motion to Exclude Certain Case Specific Opinions and Testimony of Dr. Lee Congleton ("Motion to Exclude"). [Doc. 92]. The parties appeared before the undersigned for a motion hearing on July 2, 2021. Attorneys Adam Davis and Diane Watkins appeared on behalf of Plaintiff. Attorneys Amy Pepke and Kari Sutherland appeared on behalf of Defendants. Accordingly, for the reasons discussed below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion to Limit [**Doc. 90**] and **DENIES** Plaintiff's Motion to Exclude [**Doc. 92**].

I. BACKGROUND

In December 2011, Plaintiff underwent an operation at Harton Regional Medical Center in Tullahoma, Tennessee, performed by Dr. Murphy to implant a medical device, TVT-O device ("Device"). [Doc. 1]. Plaintiff alleges that she sustained various injuries because of the Device, including pelvic pain and urinary tract infections ("UTIs"). Plaintiff has pending claims against

Defendants for negligence, strict liability for failure to warn, strict liability for defective product, strict liability for design defect, common law fraud, fraudulent concealment, constructive fraud, negligence misrepresentation, negligent infliction of emotional distress, breach of express and implied warranty, gross negligence, punitive damages, and discovery rule and tolling. *See* [*id*.].

Relevant to the instant matter, Plaintiff has retained Bruce Rosenzweig, M.D., a urogynecologist, to provide case-specific expert testimony, and Defendants have retained a urologist, Lee Congleton, M.D., to provide expert opinions in this matter. Each party has challenged the opposing party's expert's opinions.

II. STANDARD OF REVIEW

"Federal Rule of Evidence 702 obligates judges to ensure that any scientific testimony or evidence admitted is relevant and reliable." *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 147 (1999) (quoting *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579, 589 (1993)). Specifically, Rule 702 provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert,* the Supreme Court of the United States stated that a district court, when evaluating evidence proffered under Rule 702, must act as a gatekeeper, ensuring "that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589. The *Daubert* standard "attempts to strike a balance between a liberal admissibility standard for relevant evidence on the one hand and the need to exclude misleading 'junk science' on the other." *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 176–77 (6th Cir. 2009).

The factors relevant in evaluating the reliability of the testimony, include: "whether a method is testable, whether it has been subjected to peer review, the rate of error associated with the methodology, and whether the method is generally accepted within the scientific community." *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 970-71 (M.D. Tenn. 2002) (citing *Daubert*, 509 U.S. at 593–94). Rule 702 inquiry as "a flexible one," and the *Daubert* factors do not constitute a definitive checklist or test. *Kumho Tire Co.*, 526 U.S. at 138-39 (citing *Daubert*, 509 U.S. at 593); *see also Heller v. Shaw Indus., Inc.,* 167 F.3d 146, 152 (3d Cir. 1999) (explaining that these factors "are simply useful signposts, not dispositive hurdles that a party must overcome in order to have expert testimony admitted").

"Although *Daubert* centered around the admissibility of scientific expert opinions, the trial court's gatekeeping function applies to all expert testimony, including that based upon specialized or technical, as opposed to scientific, knowledge." *Rose v. Sevier Cty., Tenn.*, No. 3:08-CV-25, 2012 WL 6140991, at *4 (E.D. Tenn. Dec. 11, 2012) (citing *Kumho Tire Co.*, 526 U.S. at 138-39). "[A] party must show, by a 'preponderance of proof,' that the witness will testify in a manner that will ultimately assist the trier of fact in understanding and resolving the factual issues involved in the case." *Coffey*, 187 F. Supp. 2d at 70-71 (quoting *Daubert*, 509 U.S. at 593-94). The party offering the expert has the burden of proving admissibility. *Daubert,* 509 U.S. at 592 n. 10.

Moreover, the Supreme Court has explained that in determining "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact," the court must assess "whether the reasoning or methodology underlying the testimony is scientifically valid and whether it can properly be applied to the facts in issue." *Id.* at 592–93. "Furthermore, the court must examine the expert's conclusions in order to determine whether they can reliably follow from the facts known to the expert and the methodology used." *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *7 (E.D. Pa. Feb. 1, 2001) (citing *Heller,* 167 F.3d at 153).

Further, a court should "exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise." *In re Diet Drugs*, 2001 WL 454586, at *7 (quoting 4 Weinstein's Fed. Evid. § 702.06[1], at 702–52 (2000)). This simply means that "a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue." *Id.* (other citations omitted).

Finally, "the court will not exclude expert testimony merely because the factual bases for an expert's opinion are weak." *Andler v. Clear Channel Broad., Inc.*, 670 F.3d 717, 729 (6th Cir. 2012) (quotation marks and citations omitted). Exclusion is the exception, not the rule, and "the gatekeeping function established by *Daubert* was never 'intended to serve as a replacement for the adversary system.'" *Daniels v. Erie Ins. Group*, 291 F. Supp. 3d 835, 840 (M.D. Tenn. Dec. 4, 2017) (quoting *Rose v. Matrixx Initiatives, Inc.*, No. 07–2404–JPM/tmp, 2009 WL 902311, at *7 (W.D. Tenn. March 31, 2009)) (other quotations omitted). Rather, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert,* 509 U.S. at 596. Rule 702 does not "require anything approaching absolute certainty." *Daniels*, 291 F. Supp. 3d at 840 (quoting *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671–72 (6th Cir. 2010)).

III. ANALYSIS

The Court has considered the parties' positions and the oral arguments presented at the hearing. Accordingly, for the reasons explained below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion [**Doc. 90**] and **DENIES** Plaintiff's Motion [**Doc. 92**].

The Court will first address Defendants' challenges to Dr. Rosenzweig's opinions and then turn to Plaintiff's challenges to Dr. Congleton's opinions.

A. Dr. Rosenzweig

Defendants assert five challenges to Dr. Rosenzweig's testimony. First, Defendants argue that Dr. Rosenzweig's opinions regarding alternatives to the Device should be excluded as they do not constitute safer alternative designs. Second, Defendants argue that Dr. Rosenzweig's opinions concerning degradation, deformation, and other alleged characteristics of the Device should be excluded because they are unreliable. Third, Defendants state that Dr. Rosenzweig should not be allowed to speculate on what Plaintiff's implanting physician knew prior to the surgery. Fourth, Defendants argue that Dr. Rosenzweig cannot render any legal conclusions. Finally, Defendants assert that Dr. Rosenzweig cannot testify as to the reasonableness and necessity of Plaintiff's medical charges.

The Court will consider these challenges separately.

1. Alternatives to the Device

Defendants argue that Dr. Rosenzweig's opinions regarding alternatives to the Device should be excluded because he identifies procedures and not safer alternative designs. Defendants state that Plaintiff is not required to present proof of an alternative design under Tennessee law, but should she choose to do so, the proof must be relevant, citing to *King v. Danek Medical, Inc*.,

37 S.W.3d 429 (Tenn. Ct App. 2000). Defendants argue that the MDL court precluded another expert from offering a similar opinion.

Plaintiff agrees that Tennessee law does not require her to prove the existence of a safer alternative design to establish a prima facie case under the Tennessee Products Liability Act. Plaintiff argues, however, that Dr. Rosenzweig's proposed alternatives are relevant for other reasons. For example, Plaintiff contends that in states that allow claims based on design defects, the existence of an alternative procedure is relevant to the utility of the design and whether there was a better way to solve the problem the Device is supposed to treat. In addition, Plaintiff states that the alternatives bear on whether it was reasonable to bring the Device into the market and to rebut Defendants' assertion that the TVT-O is the "gold standard" for treatment. Plaintiff also asserts that Dr. Rosenzweig has offered several products as safer alternatives.

Defendants reply that Plaintiff has not established that the alternative surgical procedures are relevant under Tennessee law.

In the present matter, Dr. Rosenzweig opines as follows:

> Safer alternative designs, rather than the TVT polypropylene mesh product, existed for this patient. I have experience with many of these safer alternative designs, and based on my experience and review of medical literature and other materials, it is my opinion that these alternative designs were safer and feasible for Ms. Wilder. These safer alternative designs include:
>
> - Autologous fasica lata and autologous fascia sling;
> - An allograft sling such as Repliform;
> - A sling with less polypropylene such as Ultrapro; and
> - A Burch Procedure.

[Doc. 90-2 at 11-12]. Dr. Rosenzweig concludes, "These safer alternative designs would have significantly reduced the risk of the injuries to Ms. Wilder, as I have described in my report, that were a result of the specific design flaws of the TVT-O." [*Id.* at 12].

As mentioned above, Defendants object to the above testimony, arguing that it is irrelevant because Dr. Rosenzweig offers procedures and not designs, and Plaintiff responds that such testimony is relevant for other reasons. As an initial matter, the Court notes that the parties agree that under the Tennessee Products Liability Act, Plaintiff is not required to prove the existence of an alternative design. Plaintiff insists that Dr. Rosenzweig's opinion is relevant to the utility of the design.

The Tennessee Products Liability Act states, in part, as follows, "A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a). In determining if a product is defective or unreasonably dangerous, "Consideration is given also to the customary designs, methods, standards, and techniques of manufacturing, inspecting, testing by other manufacturers or sellers of similar products." Tenn. Code Ann. § 29-28-105(b).

The Court finds evidence of other procedures, as opposed to designs or products, irrelevant and confusing to the jury. *Hosbrook v. Ethicon, Inc.*, No. 3:20-CV-88, 2021 WL 1599199, at *4 (S.D. Ohio Apr. 23, 2021) ("To introduce evidence of alternative surgical procedures in a product liability case is irrelevant and would create confusion for the jury."). The Court agrees with Defendants that offering alternative procedures takes issue with Plaintiff's physician's treatment choices as opposed to the alleged issues with the Device. *See Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 907 (S.D. Iowa 2020) ("The choice of a surgery over a device is a matter of

medical judgment of treating doctors, not whether there is a safer alternative design for the product."). In addition, the Tennessee statute states that consideration should be given "to the customary designs, methods, standards, and techniques of manufacturing, inspecting, testing by other manufacturers or sellers of similar products." Tenn. Code Ann. § 29-28-105(b).

In support of her position, Plaintiff argues that both alternative procedures and designs are relevant to the risk-utility test utilized in Tennessee. The Tennessee Products Liability Act provides for two tests to determine whether a product is unreasonably dangerous: the consumer expectation test and the prudent manufacturer test. *Brown v. Crown Equip. Corp.*, 181 S.W.3d 268, 282 (Tenn. 2005). The prudent manufacture test requires courts to consider the risk-utility of the product by balancing several factors, including the product's usefulness and desirability. *Id.* Here, the Court does not find evidence of alternative procedures relevant to the Device's usefulness and desirability for the reasons described above. *Id.* The Court also finds such evidence misleading and confusing in a products liability case.[1]

With respect to Dr. Rosenzweig's safer alternative designs, the parties also dispute whether he has offered similar products. The main point of contention appears to be whether a substitute of natural material for synthetic material makes the product wholly different. During the motion hearing, Defendants explained that a native tissue repair is a procedure because a physician simply attaches the tissue with sutures. In addition, Defendants explained that the slings Dr. Rosenzweig mentions can either be made with the patient's own tissue (autologous slings) or with tissue from a cadaver (allograft slings). Defendants stated that these slings are not similar to the syntenic mesh

[1] Defendants acknowledged at the hearing that their witnesses will not testify that the TVT-O device was the "gold standard," and that if they did testify to such, the testimony would open to the door to the evidence that they requested be excluded.

at issue and that the slings are regulated differently. The Court will not preclude Dr. Rosenzweig from testifying about the slings. The Court finds that the slings are relevant to the risk-utility analysis and that the differences between the Device at issue and the slings are facts that the jury should consider. In support of their position, Defendants rely on *King*, wherein the Tennessee Court of Appeals granted summary judgment to defendant on plaintiff's claim that a product was unreasonably dangerous, stating that the expert did not propose an alternative design but instead recognized dissimilar devices that did not use pedicle screws. 37 S.W.3d at 449. The Court notes, however, that *King* was decided on a dispositive motion, and here, the question is simply whether a product using non-syntenic material is relevant to the risk-utility analysis. The Court finds that it is relevant for the jury to consider.

Defendants also objected to Dr. Rosenzweig's opinion that Ultrapro is a safer alternative design, arguing his opinion is not reliable. Defendants stated at the hearing that Dr. Rosenzweig did not cite any studies to support his opinion and that the Federal Drug Administration denied authorization of Ultrapro during the relevant time period. As Plaintiff noted at the hearing, the MDL Court allowed Dr. Rosenzweig to offer the Utrapro mesh as an alternative. *See Ellis v. Ethicon,* No. 2:20-cv-223-CEA-HBG [Doc. 66-20 at 7-8]. With respect to Defendants' arguments regarding FDA approval, the Court finds that those are better addressed through cross examination. Accordingly, the Court finds Defendants' Motion on this issue well taken, in part, and therefore, it is **GRANTED IN PART AND DENIED IN PART.**

2. Characteristics of the Device

Defendants assert that Dr. Rosenzweig's opinions concerning the degradation, deformation, and other alleged characteristics of Plaintiff's Device should be excluded. Defendants contend that there is no reliable evidence that Plaintiff's Device sustained these

conditions because there is no pathology or medical evidence that suggest such conditions. Defendants state that Dr. Rosenzweig did not conduct an independent medical evaluation and that his opinion that it is possible that the Device may undergo these conditions is irrelevant and prejudicial. Defendants argue that Dr. Rosenzweig cannot provide causation opinions based on the mere possibility of such conditions occurring.

Plaintiff relies on the MDL court's ruling that allowed Dr. Rosenzweig to provide such opinions without a pathology report. Plaintiff asserts that Dr. Rosenzweig has studied mesh degradation in the scientific literature and has experience in his own practice. Plaintiff argues that Dr. Rosenzweig applied his general knowledge to the specific facts associated with Plaintiff's medical history and injury to perform a differential diagnosis.

Defendants reply that Tennessee law does not allow causation to be established by mere inference but instead requires Plaintiff to trace her injuries to a specific product defect. Defendants state that Dr. Rosenzweig cites no evidence from Plaintiff's medical records and offers no explanation for his conclusion.

Specifically, Defendants challenge Dr. Rosenzweig's opinions that Plaintiff's Device sustained degradation, deformation, rigidity, fraying, roping, cording, and curling, loss of pore size, fibrotic bridging, and shrinkage/contraction, and therefore, Plaintiff was injured. [Doc. 90-2 at 10-11]. In his expert report, Dr. Rosenzweig outlines his professional experience, which includes performing over one thousand pelvic floor surgical procedures. [*Id*. at 3]. In his surgeries, he has used numerous synthetic pelvic mesh products, including the Device here, and has also removed numerous TVT-O devices. [*Id.* at 3-4]. Dr. Rosenzweig explains Plaintiff's medical history in detail. [*Id.* at 4-8]. He states that he performed a differential diagnosis to arrive at his conclusions. [*Id.* at 9] ("In determining the cause of a specific injury, it is necessary to 'rule in'

potential causes of the injury, and then by process of elimination, to 'rule out' the least likely causes in order to arrive at the most likely cause."). Dr. Rosenzweig states that Plaintiff's medical and surgical history did not increase the risk for developing her symptoms. [*Id.*]. Dr. Rosenzweig provides a list of the polypropylene mesh characteristics and opines that contraction, shrinkage, deformation, and degradation, and rigidity of the TVT-O, the materials used to manufacture the TVT-O, and the design of the TVT-O, or a combination of these factors, caused [Plaintiff's] injuries. [*Id.* at 11].

The Court finds Defendants' objections go to the weight of Dr. Rosenzweig's testimony, rather than to its admissibility. Defendants argue that there is no medical evidence or pathology to establish that Plaintiff's Device demonstrated degradation, deformation, and other characteristics. The Court does not find the lack of a pathology report fatal to Dr. Rosenzweig's opinions. Dr. Rosenzweig reviewed Plaintiff's medical history and performed a differential diagnosis. The Sixth Circuit Court of Appeals has held that a "medical-causation opinion in the form of a doctor's differential diagnosis is reliable and admissible, where the doctor: (1) objectively ascertains, to the extent possible, the nature of the patient's injuries; (2) 'rules in' one or more causes of the injury using a valid methodology; and (3) engages in 'standard diagnostic techniques by which doctors normally rule out alternative causes' to reach a conclusion as to which cause is most likely." *Best v. Lowe's Home Centers, Inc.,* 563 F.3d 171, 179 (6th Cir. 2009) (quoting *In re Paoli Railroad Yard PCB Litig.,* 35 F.3d 717 (3d Cir. 1994)). Accordingly, the Court finds Dr. Rosenzweig's opinion reliable.

The Western District of Texas addressed similar arguments regarding Dr. Rosenzweig's opinion. *See Meindertsma v. Ethicon Inc*., No. 1:20-CV-00708-RP, 2021 WL 2010355, at *7 (W.D. Tex. May 17, 2021). Specifically, in *Meindertsma*, Ethicon argued that Dr. Rosenzweig's

opinions were unreliable because there was no evidence that degradation, deformation, rigidly, fraying, and other characteristics existed in the specific device that the surgeon implanted in plaintiff. *Id*. The court disagreed. *Id*. The court held that although Dr. Rosenzweig did not personally examine the mesh or the plaintiff, his differential diagnosis was reliable and that Ethicon's challenges were to the weight of the opinion. *Id.*

Similarly, in the instant matter, Dr. Rosenzweig discussed the conditions he was able to rule out and established a basis for ruling in the characteristics of the mesh that causes the type of injuries that Plaintiff allegedly suffered. Defendants may cross examine Dr. Rosenzweig regarding his opinions and present contrary evidence. Accordingly, Defendants' arguments are not well taken, and the Motion on this issue is **DENIED**.

3. Knowledge of the Implanting Physician

Defendants argue that Dr. Rosenzweig should be precluded from speculating on what Plaintiff's implanting physician knew prior to surgery. Defendants argue that Tennessee has adopted the learned intermediary defense and that the MDL court consistently excluded testimony regarding what physicians know or should know about specific topics.

Plaintiff responds that Dr. Rosenzweig is qualified to opine on the inadequacy of the warnings and that Plaintiff could not make an informed decision because her physician was not given sufficient information. Plaintiff states that Dr. Rosenzweig is qualified to provide opinions about the product warnings for the transvaginal mesh devices given his experience with the development of warning labels and IFUs.

Defendants reply that opinions regarding Plaintiff's implanting physician's knowledge and state of mind should be excluded. Defendants argue that while Plaintiff attempts to characterize

Dr. Rosenzweig's opinions as to the adequacy, completeness, and accuracy of the IFU, his report clearly seeks to offer testimony regarding the implanting surgeon's knowledge.

In the present matter, Dr. Rosenzweig opines that Plaintiff "was not able to make a fully informed medical decision regarding the implantation of the TVT-O mesh because Ethicon failed to fully disclose the risks and complications (both early and late) in the TVT-O IFU." [Doc. 90-2 at 12]. Dr. Rosenzweig continues as follows:

> As discussed in the general liability reports, [Plaintiff] did not receive information about the risks and complications because Ethicon did not disclose them fully in its IFUs, and surgeons, including the implanting surgeon in [Plaintiff's] case, were not made aware of them. This is true despite information readily available to Ethicon about these risks, which predate the launch of the device. Because of this, [Plaintiff's] implanting surgeon could not pass this information on to her and properly consent about the risks associated with the TVT-O deice. [Plaintiff] was unable to make a fully informed decision about having the devices implanted.

[*Id.*]. Dr. Rosenzweig concludes as follows, "As a result, to a reasonable degree of medical certainty, [Plaintiff] suffered injuries that were not disclosed by Ethicon, and the inadequate disclosure of these risks was a substantial factor and/or cause of [Plaintiff's] injuries." [*Id.*].

As mentioned above, Defendants challenge Dr. Rosenzweig's opinions that discuss Plaintiff's implanting physician's knowledge and state of mind, while Plaintiff responds that Dr. Rosenzweig is qualified to opine on the inadequacy of the warnings that accompanied the Device. The Court finds that Dr. Rosenzweig may not testify about the awareness or knowledge of Dr. Murphy, the implanting physician. *See Bell v. Ethicon Inc.,* No. 4:20-CV-3678, 2021 WL 1111071, at *8 (S.D. Tex. Mar. 23, 2021) (excluding Dr. Rosenzweig's testimony regarding what the implanting surgeon knew or did not know at the time of plaintiff's surgery); *Nall v. C. R. Bard, Inc.,* No. 2:13-CV-01526, 2018 WL 524632, at *2 (S.D.W. Va. Jan. 23, 2018) ("The defendant

argues that I should preclude Dr. Rosenzweig from testifying as to the state of mind of the plaintiff and Dr. Foster, her implanting physician. I agree; experts may not testify about what other parties did or did not know."). The Court finds that the jury can evaluate Dr. Murphy's testimony about his knowledge of the risks at the time of Plaintiff's implant procedure.[2] Accordingly, Defendants' request is well taken, and the Motion on this issue is **GRANTED**.

4. Legal Conclusions

Defendants object to Dr. Rosenzweig's statement that Plaintiff has suffered and will continue to suffer damages. Defendants argue that this statement is a legal conclusion and that the MDL court already held that the experts cannot render legal conclusions. Plaintiff states that Dr. Rosenzweig does not intend to offer the above statement at trial. Accordingly, given Plaintiff's representation, the Court finds that Defendants' argument is moot, and the Motion on this issue is **DENIED AS MOOT.**

5. Reasonableness and Necessity of Plaintiff's Medical Charges

Defendants request that the Court preclude Dr. Rosenzweig's opinion on the reasonableness and necessity of Plaintiff's medical charges. Defendants argue that Dr. Rosenzweig's opinion is conclusory and that Dr. Rosenzweig is based out of Chicago, Illinois, and he does not have knowledge of the market in which Plaintiff received her care. During the motion hearing, Defendants cited *Dedmon v. Steelman*, 535 S.W.3d 431 (Tenn. 2017) in support of their position.

Plaintiff states that there is no legal authority for excluding Dr. Rosenzweig's opinions regarding the reasonableness and necessity of Plaintiff's medical charges. Plaintiff states that

[2] Defendants also argue that whether Plaintiff was able to make a fully informed decision is irrelevant given the claims asserted here, but Defendants do not explain this argument.

Defendants can cross examine Dr. Rosenzweig's opinions. In her Supplemental Brief [Doc. 112], Plaintiff argued that there has been no evidence that the treatment options in Tennessee are different from the options in other places.

In the present matter, Dr. Rosenzweig states that he has reviewed Plaintiff's medical bills and that he "feel[s] that they were reasonable and necessary charges to treat the complications and injuries that, to a reasonable degree of medical certainty, were caused by the TVT-O device . . ." [Doc. 90-2 at 13].

In *Dedmon v. Steelman*, the Supreme Court noted that in order for a plaintiff to recover past medical expenses, a plaintiff must show that the medical bills paid or accrued were both "necessary and reasonable." 535 S.W.3d at 438 (other citations omitted). "In all but the most obvious and routine cases, plaintiffs must present competent expert testimony to meet this burden of proof." *Borner v. Autry*, 284 S.W.3d 216, 218 (Tenn. 2009). "To be qualified to render these opinions, the physician must first demonstrate (1) knowledge of the party's condition, (2) knowledge of the treatment the party received, (3) knowledge of the customary treatment options for the condition in the medical community where the treatment was rendered, and (4) knowledge of the customary charges for the treatment." *Dedmon*, 535 S.W.3d at 438 (quoting *Long v. Mattingly*, 797 S.W.2d 889, 893 (Tenn. Ct. App. 1990)).

In *Nash v. Carter*, the Tennessee Court of Appeals held that "an out-of-town referring physician could not testify to the reasonableness of the charges of a hospital where he does not practice or the charges of physicians in a city where he does not practice." No. 87-192-II, 1987 WL 19312, at *6 (Tenn. Ct. App. Nov. 4, 1987); *see also Ford v. Markert*, No. 01A01-9404-CV-00185, 1995 WL 1693, at *3 (Tenn. Ct. App. Jan. 4, 1995) ("Dr. Lamb's testimony unequivocally establishes that he is not familiar with the customary treatment options and charges relating to

[plaintiff's] condition in the medical communities of Dodge City or Garden City, Kansas or Paducah, Kentucky. Hence, he was not qualified to render an opinion as to the necessity of the services provided and the reasonableness of the charges incurred. We conclude that the admission of this testimony was harmful error."); *compare with Long v. Mattingly*, 797 S.W.2d 889, 894 (Tenn. Ct. App. 1990) (finding both physicians were competent to testify to the reasonableness of the charges because they were familiar with the charges of the treatment plaintiff received and within the area where plaintiff received such treatment).

In the instant matter, there is no evidence before the Court that Dr. Rosenzweig is familiar with the reasonableness and necessity of Plaintiff's medical charges within the community where she was treated. During oral argument, Plaintiff stated that Dr. Rosenzweig has treated patients across the country, but the Court has no evidence that he is familiar with the medical charges where Plaintiff was treated. The Court finds Dr. Rosenzweig cannot testify about the reasonableness and necessity of Plaintiff's medical charges. Accordingly, the Court finds Defendants' argument well taken, and the Motion on this issue is **GRANTED**.

B. Dr. Congleton

Plaintiff submits two challenges to Dr. Congleton's opinions. First, Plaintiff requests that the Court exclude Dr. Congleton's opinion that the Device cannot be the cause of Plaintiff's chronic pelvic pain or that the Device cannot migrate. Plaintiff states that Dr. Congleton relied on his experience in forming this conclusion, but he never identifies any data regarding the number of implants or revision surgeries in which he was involved. Plaintiff submits that if a witness relies on his/her own experience, the witness must explain the experience that leads to that conclusion, why the experience is a sufficient basis for that opinion, and how that experience is reliably applied

to the facts. In addition, Plaintiff states that Dr. Congleton's publications and presentations address male urinary and prostate issues but not female issues.

In a similar vein, Plaintiff argues that the Court should exclude Dr. Congleton's opinion about the safety and efficiency of the Device because he based these opinions upon his experience, but his opinions are not supported by a reliable methodology or subject to peer review. Plaintiff argues that Dr. Congleton acknowledged that he never asked for or reviewed internal Ethicon documents related to the injuries caused by the Device.

Defendants argue that Dr. Congleton's opinions are not solely based on his personal experience and that Dr. Congleton also reviewed Plaintiff's medical records and testimony, as well as the medical literature. Defendants also assert that as their expert, Dr. Congleton is not required to conduct a differential diagnosis and may point to any plausible causes of Plaintiff's alleged injuries.

Specifically, Plaintiff objects to Dr. Congleton's testimony during his deposition regarding whether the Device is causing the catch on the left side or the pain on the left side that Plaintiff is experiencing. Dr. Congleton testified that in his experience "that would be unusual." [Doc. 93-2 at 5].[3] In addition, Plaintiff objects to Dr. Congleton's deposition testimony that pelvic pain with the Device is rare based on the "hundreds of patients he has done." [*Id.* at 8]. With respect to the Device migrating, Dr. Congleton testified that he does not agree with the migration theory based on his own experience and the medical literature. [*Id.* at 6-7].

[3] Dr. Congleton's complete response to Plaintiff's question is as follows: "I think, in my experience, that would be unusual and according to the medical literature that would be very unusual, as well." [Doc. 92-3 at 5].

During the hearing, Defendants stated that Dr. Congleton will not disclose his personal complication rates and will not offer any opinions that are not disclosed in his report. Plaintiff responded that she does not dispute Dr. Congleton's ability to discuss the medical records or the literature but simply whether complications were rare or usual in his experience. Given that Dr. Congleton will not provide a specific complication rate, the Court finds Plaintiff's request not well taken. Further, the Court will not prohibit from Dr. Congleton from using certain words (i.e., "rare" or "unusual") when describing his own personal observations. *See* [Doc. 93-1 at 3] (Dr. Congleton explaining that his opinions are based, in part, on his personal experience in private practice). Plaintiff may cross examine Dr. Congleton with respect to such issues. Plaintiff's Motion to Exclude is **DENIED**.

IV. CONCLUSION

Accordingly, for the reasons explained above, Defendants' Motion to Limit the Case-Specific Testimony of Bruce Rosenzweig, M.D. [**Doc. 90**] is **GRANTED IN PART AND DENIED IN PART** and Plaintiff's Motion to Exclude Certain Case Specific Opinions and Testimony of Dr. Lee Congleton [**Doc. 92**] is **DENIED**.

IT IS SO ORDERED.

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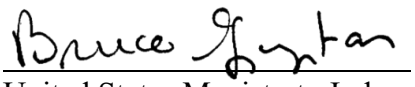

United States Magistrate Judge